M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: June 14, 1999

To: Dockets Management Branch (HFA-305)

From: Ted Sherwood
Management Analyst
Office of Generic Drugs

Subject: Presentation Regarding Human Generic Drugs to Docket 90S-0308

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Regulatory Harmonization Friend or Foe?

Presented for: International Generic Pharmaceutical Association

Date Presented: June 3, 1999

Presented by: Douglas L. Sporn

Number of Pages: 17

Ted Sherwood

Attachment

90S-0308

M642

International Generic Pharmaceutical Association

Regulatory Harmonization Friend or Foe?

Douglas L. Sporn
Director, Office of Generic Drugs
U.S. Food & Drug Administration
June 3, 1999
Barcelona, Spain

The answer depends on where you sit.

- Multinational Firms vs. "Mom & Pop" Firms

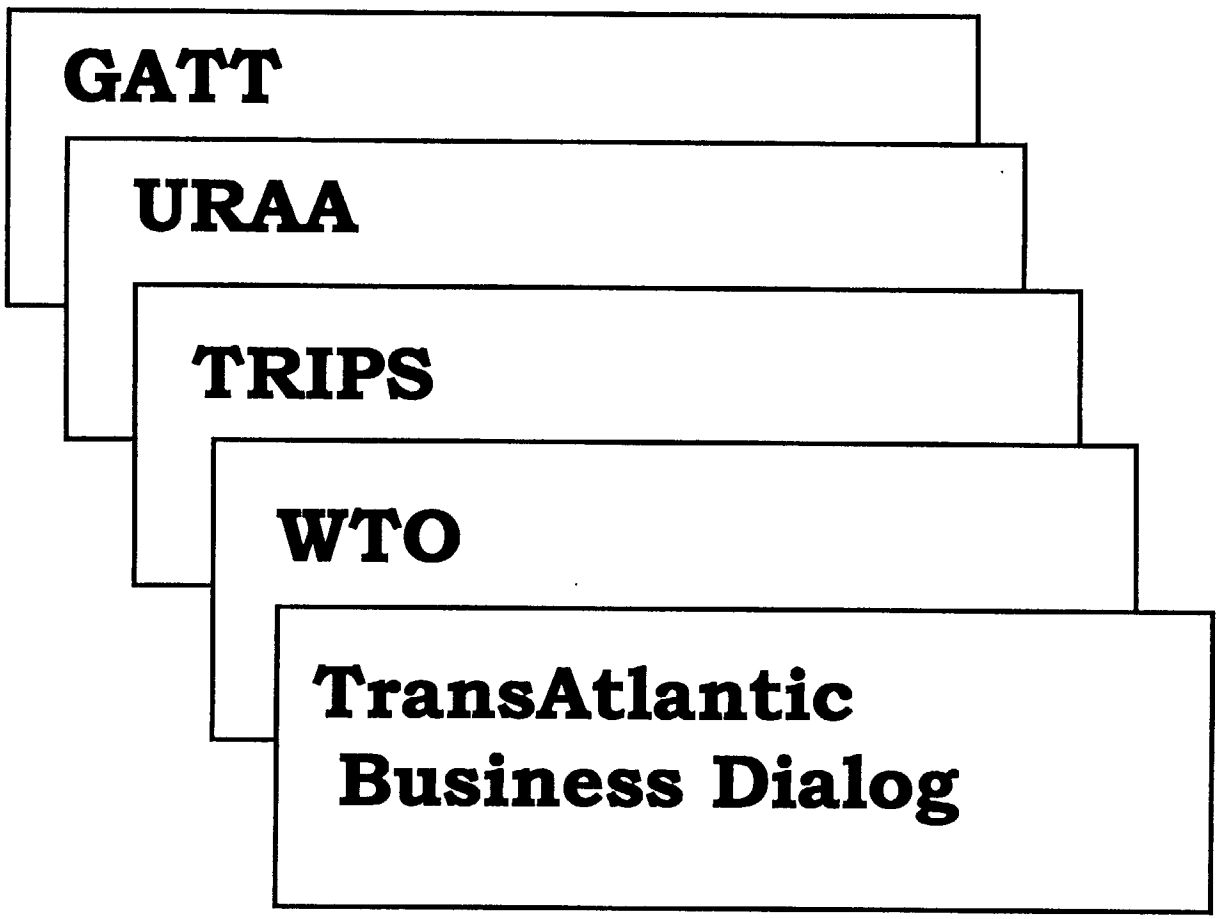
- Industry vs. National Regulators

Other Titles:

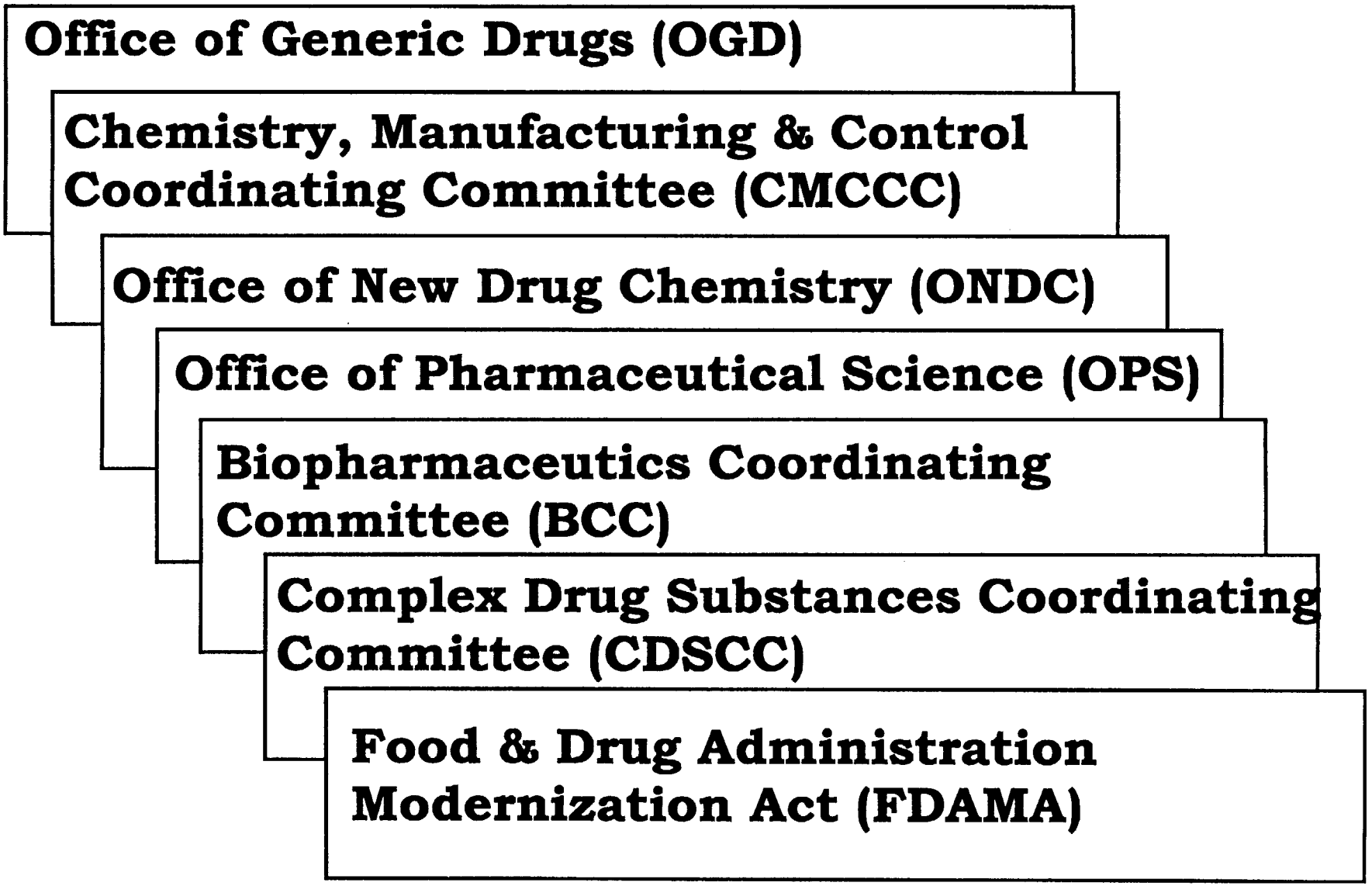
Harmonization: Winding Up or Winding Down?

Harmonization: You Ain't Seen Nothing Yet!!

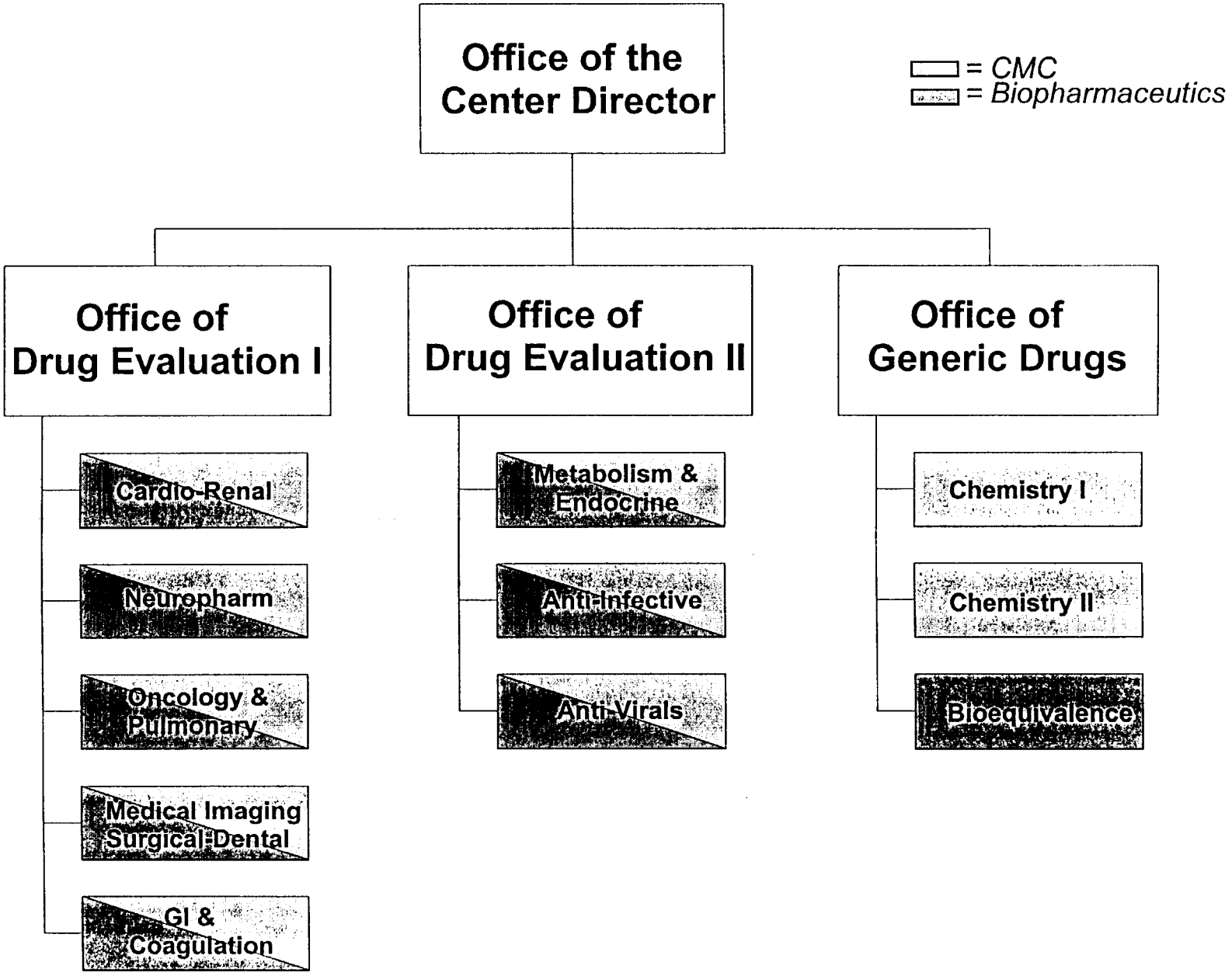
International Trade Harmonization



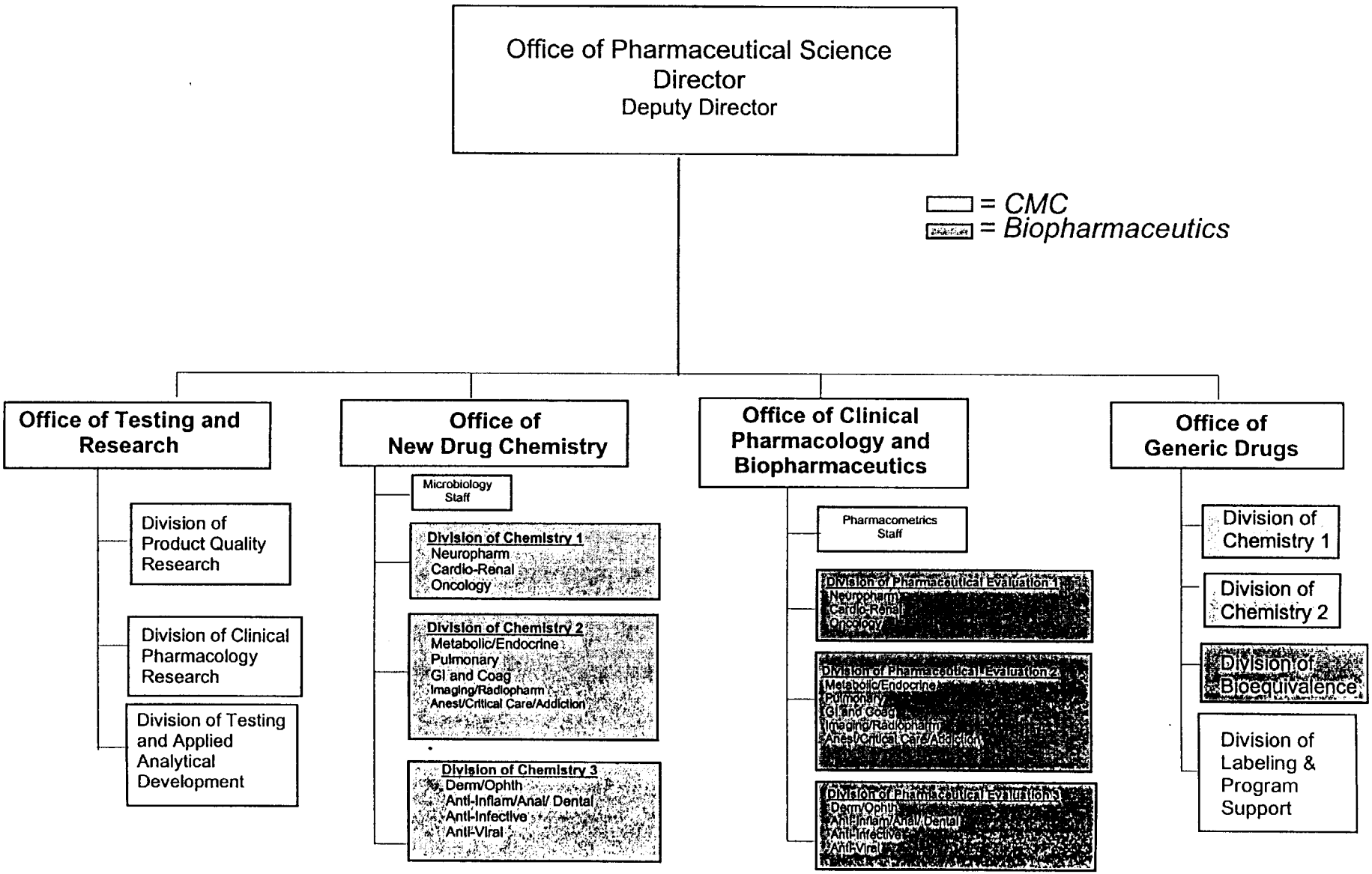
FDA Scientific & Regulatory Harmonization



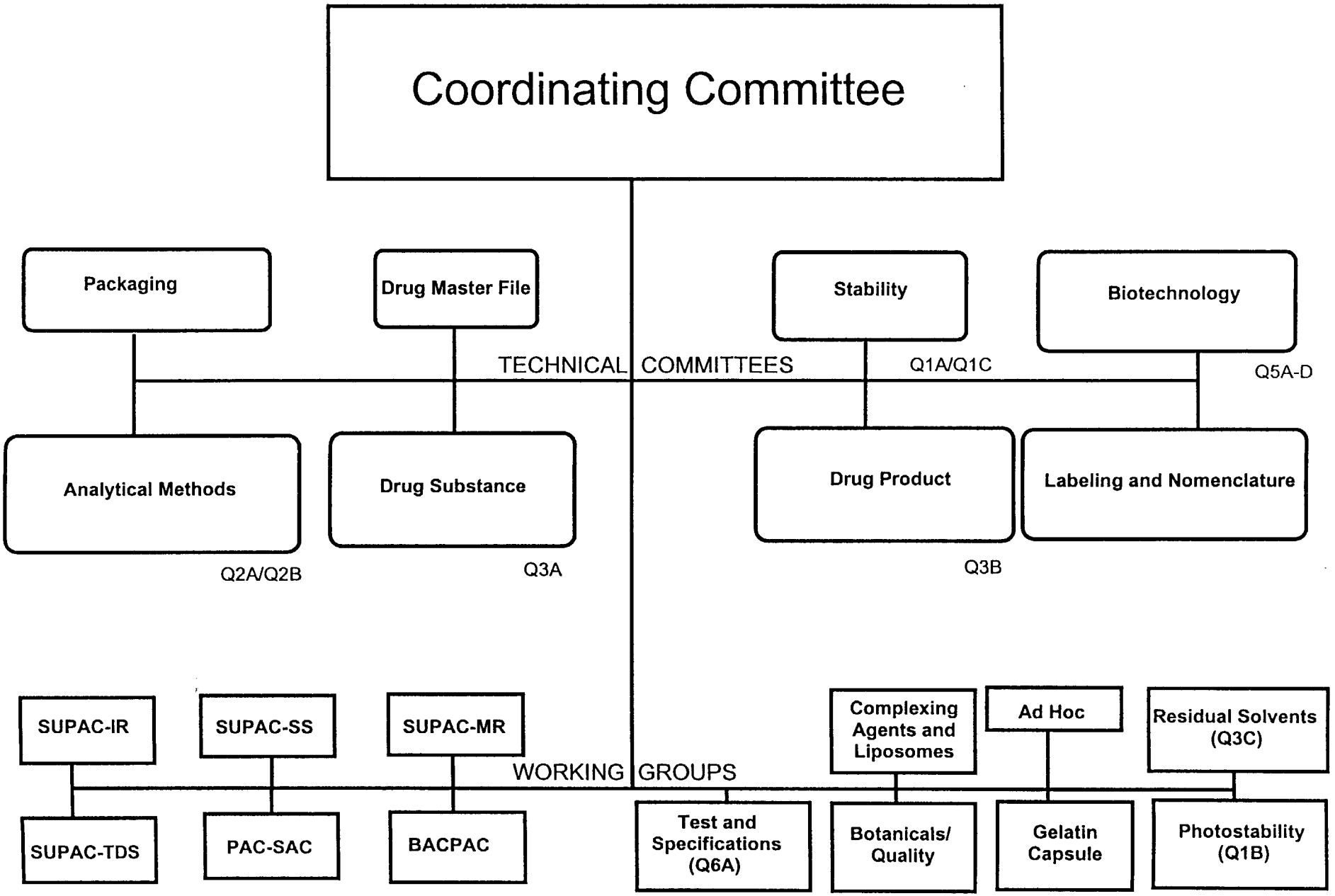
Pre-OPS Reviewing Organizations



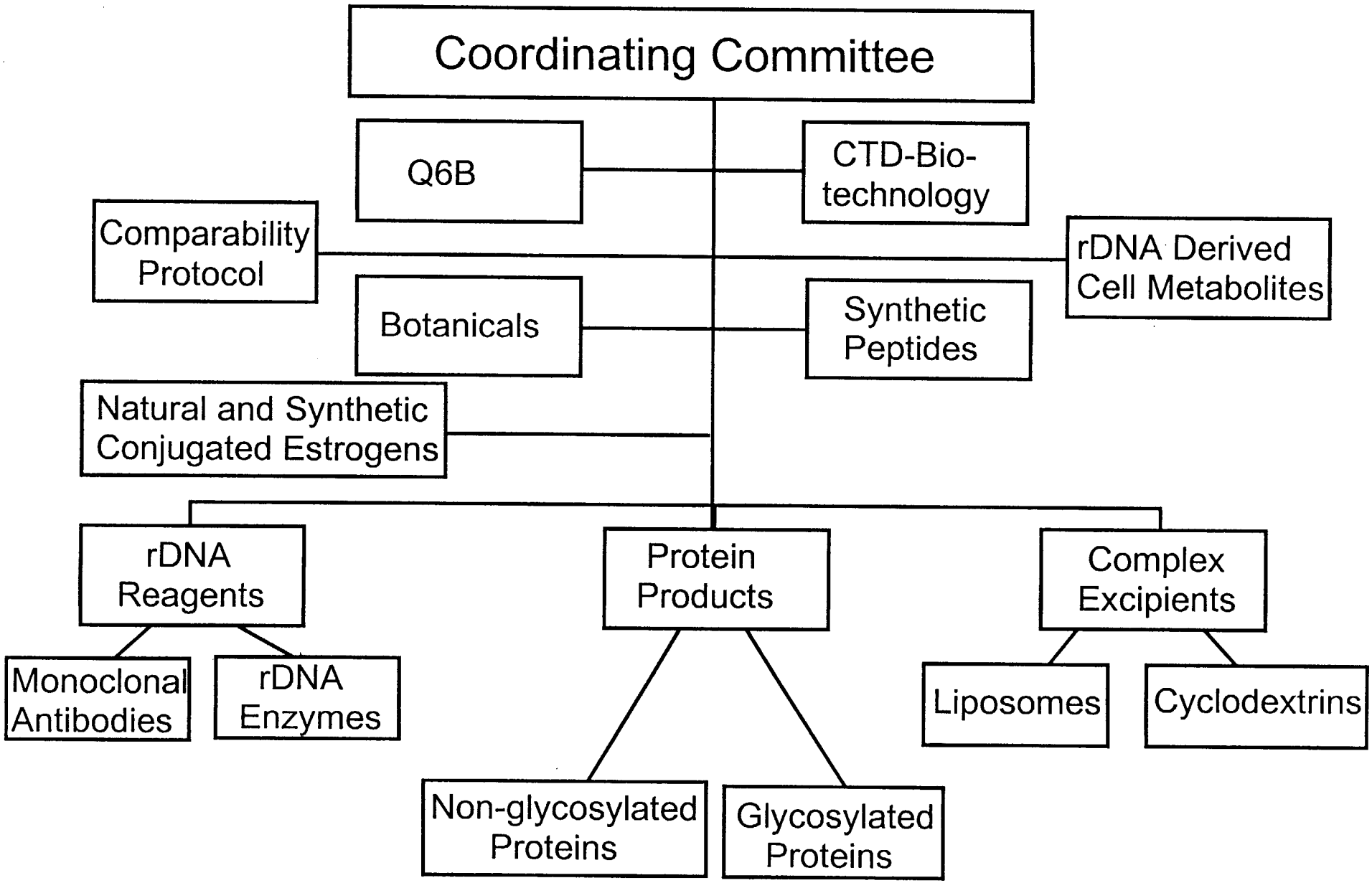
Office of Pharmaceutical Science



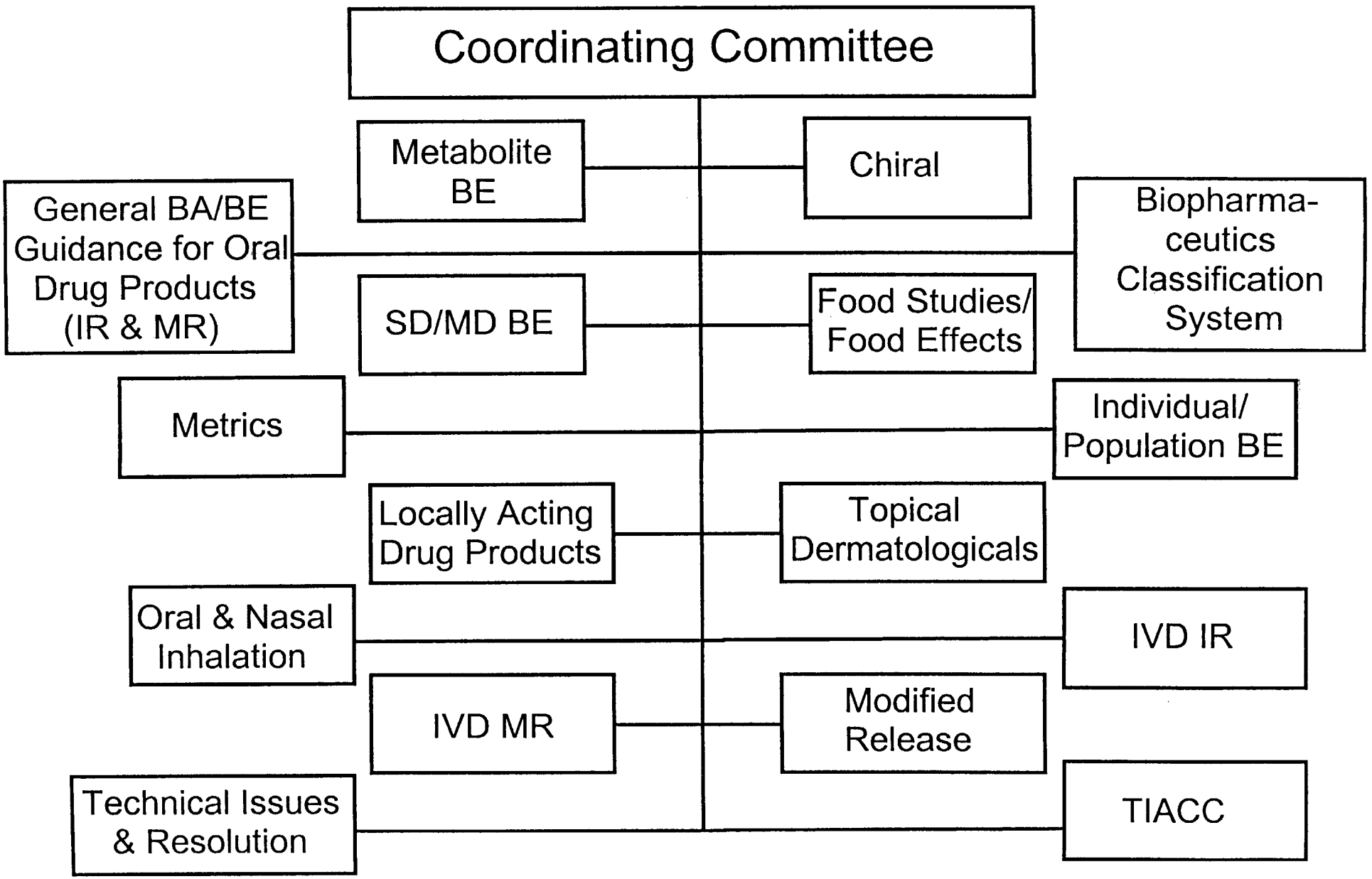
Chemistry, Manufacturing and Controls Coordinating Committee



Complex Drug Substances, Excipients, and Reagents Coordinating Committee



Biopharmaceutics Coordinating Committee



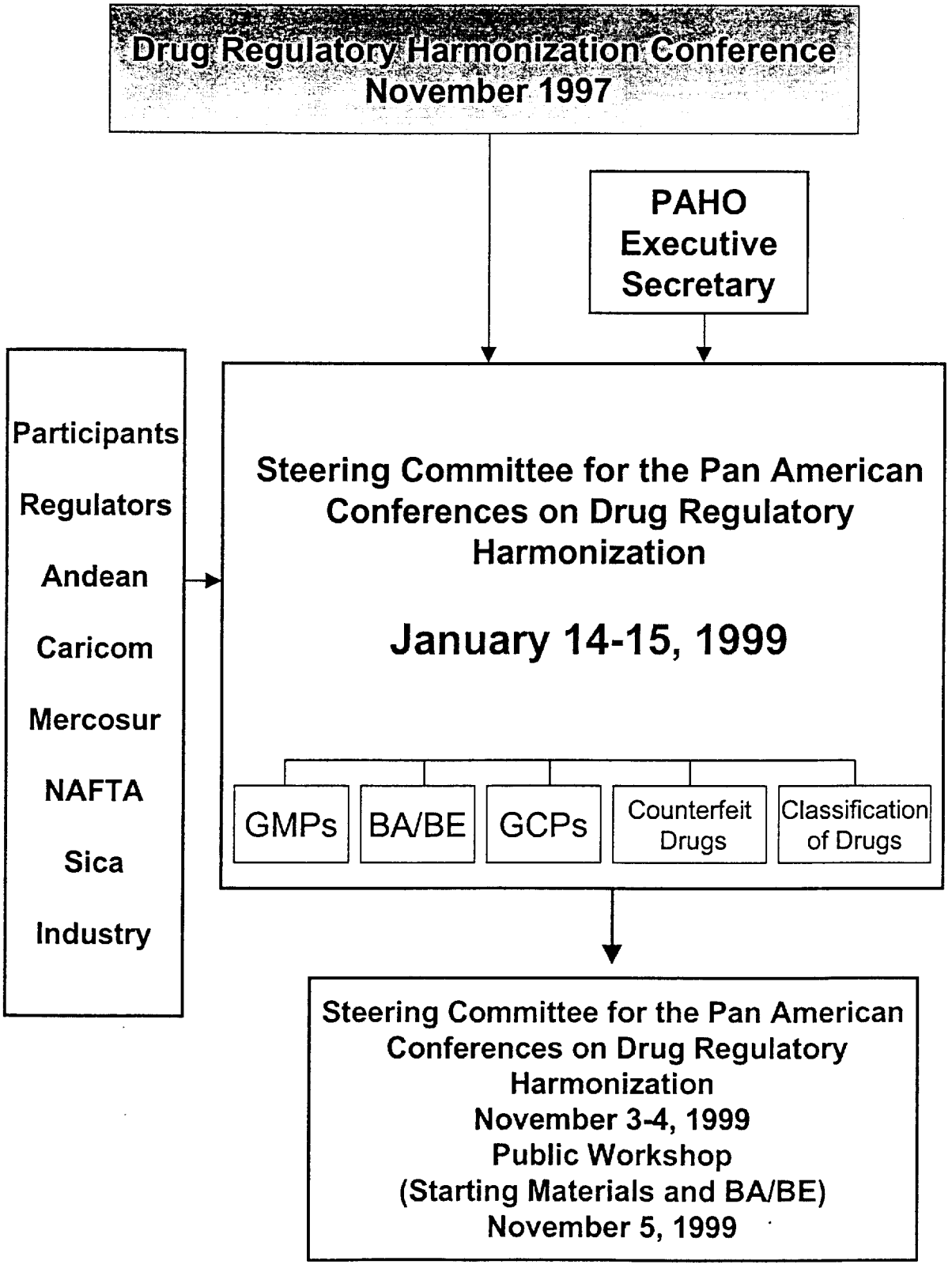
International Regulatory Harmonization

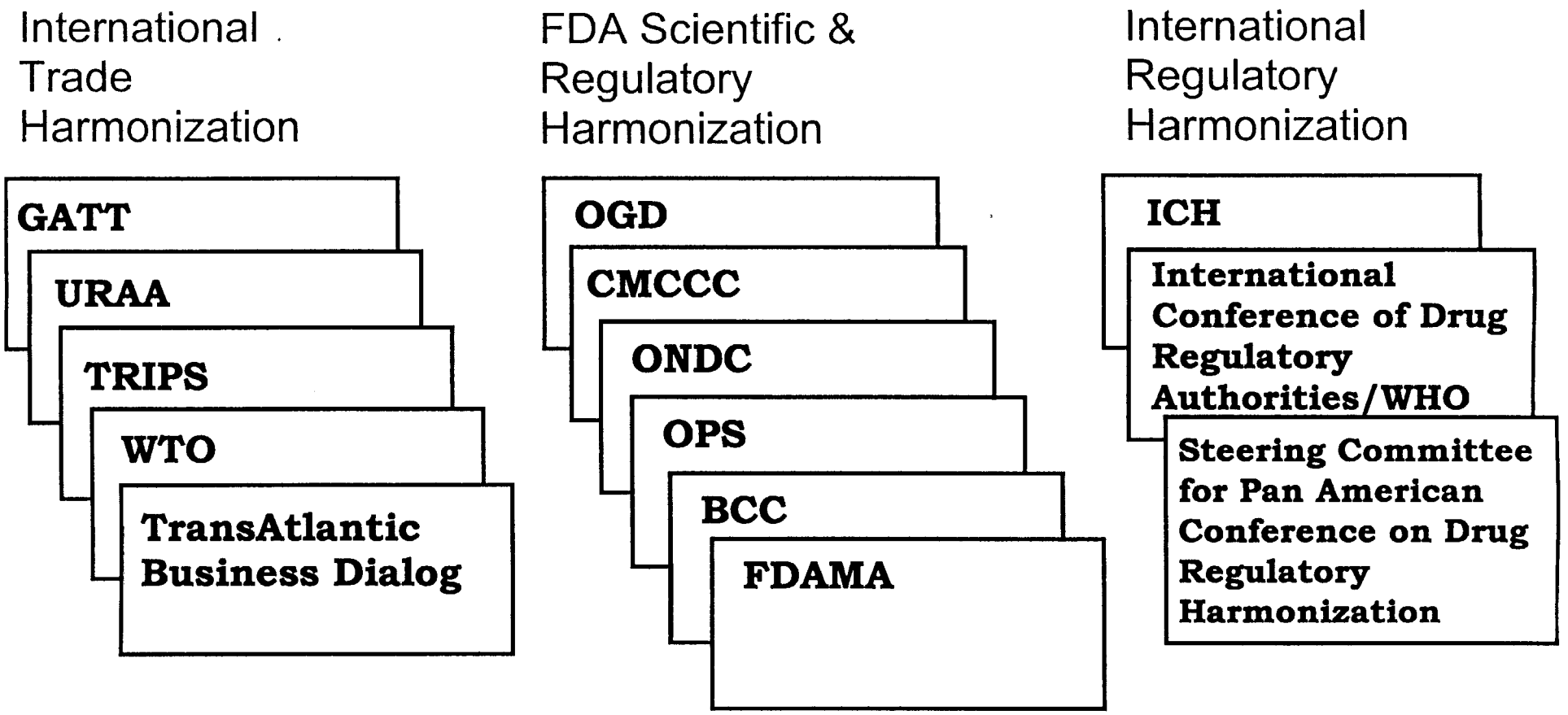
International Conference on Harmonization (ICH)

International Conference of Drug Regulatory Authorities/WHO

Steering Committee for the Pan American Conferences on Drug Regulatory Harmonization

PAHO


Drug Regulatory Harmonization Conference
November 1997
PAHO
Executive
Secretary
Participants
Regulators
Andean
Caricom
Mercosur
NAFTA
Sica
Industry
Steering Committee for the Pan American Conferences on Drug Regulatory Harmonization
January 14-15, 1999
GMPs
BA/BE
GCPs
Counterfeit Drugs
Classification of Drugs
Steering Committee for the Pan American Conferences on Drug Regulatory Harmonization
November 3-4, 1999
Public Workshop
(Starting Materials and BA/BE)
November 5, 1999


International Trade Harmonization
GATT
URAA
TRIPS
WTO
TransAtlantic Business Dialog
FDA Scientific & Regulatory Harmonization
OGD
CMCCC
ONDC
OPS
BCC
FDAMA
International Regulatory Harmonization
ICH
International Conference of Drug Regulatory Authorities/WHO
Steering Committee for Pan American Conference on Drug Regulatory Harmonization

Harmonization

Friend?	Foe?
Predictability	The Devil is in the Details!
Public Resource Savings (long term)	Public Resource Costs (short term)
Optimization of World Resources	

Harmonization

Friend?	Foe?
Competition	Competition
Lower "Break Even" Point	Higher "Break Even" Point
Reduces Some Market Barriers	Increases Market Barrier

Harmonization

Friend?	Foe?
Levels the Playing Field >More Ethical >World Citizen	Unnecessarily Elevates the Playing Field
Better Science	Not That Much Better!
Availability of More Products/Faster	
	More Difficult to Change Policy

The Decade Ahead

ICH -- Moves to harmonize on more quality topics for NME's and Generics

-- Process modified to make generics "official" members

Americas -- Trend to modern quality standards for generic drugs accelerates

WHO -- Continues to move lesser developed countries toward better, universally accepted quality standards